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| 10/576,276 | 12/28/2006 | Gea Speelmans | 0470-061182 | 9708 |
| 28289 7590 11/21/2011 THE WEBB LAW FIRM, P.C. ONE GATEWAY CENTER 420 FT. DUQUESNE BLVD, SUITE 1200 PITTSBURGH, PA 15222 | | | | |
| EXAMINER | | | | |
| PURDY, KYLE A | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1611 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 11/21/2011 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@webblaw.com

Office Action Summary**Application No.**

10/576,276

Applicant(s)

SPEELMANS ET AL.

Examiner

K P

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 19, 20 and 22-37 is/are pending in the application.
- 5a) Of the above claim(s) 24 and 31-37 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 19, 20, 22, 23 and 25-30 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-SB08)
Paper No(s) Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s) Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Status of Application

1. Claims 19, 22, 27-29 have been amended and claim 21 has been cancelled. The following rejections are made.

Response to Applicants' Arguments

2. Applicants arguments filed 7/22/2011 regarding the rejection of claim 21 made by the Examiner under 35 USC 103(a) over Cavaliere Vesely et al. (US 5895648) have been fully considered and they are found persuasive. This rejection has been overcome by cancellation of the claim.

3. Applicants arguments filed 7/22/2011 regarding the rejection of claims 19, 20, 22, 23 and 25-30 made by the Examiner under 35 USC 103(a) over Cavaliere Vesely et al. (US 5895648) have been fully considered but they are not found persuasive and are **MAINTAINED** for the reasons of record in the office action mailed on 2/24/2011.

4. In regards to the 103(a) rejection, Applicant asserts the following:

A) The rejection fails to address the chain length of carbohydrate A and the length of carbohydrate B.

5. In response to A, the Examiner is not persuaded by Applicants argument. Implicit in the definition of oligosaccharide and polysaccharide are well-understood definitions. That is, an oligosaccharide is understood as a saccharide polymer containing a small number of component sugar units, generally from about 2 to 9. Polysaccharides on the other hand are well-understood to be much larger saccharide polymers generally possessing large numbers of saccharide units,

generally at least 40. Thus, a galacto-oligosaccharide would readily be envisaged to be a saccharide polymer comprising less than 9 galactose monomers and a fructo-polysaccharide would be envisaged as containing many more units than that of an oligosaccharide, let alone 6 saccharide units. One of ordinary skill would have been motivated to adjust the number of saccharide unit for the oligosaccharide so as to provide the greatest nourishing benefit to the end user. If it were found that a oligosaccharide with between 2 and 6 units was most effective, then this would have been a result of ordinary skill and common sense. Any ordinary person of skill in the art would readily recognize the implicit definitions understood for both oligosaccharides and polysaccharides and apply them accordingly. Such an undertaking with a minor amount of optimization would result in a composition as is instantly claimed thereby obviating the instantly claimed subject matter. Applicants arguments/amendments are not persuasive.

Maintained Rejections, of Record
Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 19, 20, 22, 23 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely et al. (US 5895648; published 04/20/1999, of record).

10. Cavaliere is directed to feed compositions comprising a mixture of lyophilized live lactic bacteria and one or more oligosaccharides (see abstract). Exemplified bacteria include *Bifidobacterium breve* in a concentration of at least 50×10^9 CFU/g. more preferably 100 to 150×10^9 CFU/g (see column 3, lines 15-20). The composition is to also consist of one or **more** oligosaccharides such as galacto-oligosaccharides and inulin (a fructo-polysaccharide) (see column 4, lines 50-60). The composition may further comprise a sugar as well as milk proteins (see column 5, lines 30-65). While Cavaliere fails to exemplify a composition comprising two indigestible carbohydrates, Cavaliere suggests that the composition comprise "one or more" non-digestible carbohydrates. Thus, any ordinary person would envisage using more than one non-digestible carbohydrate such as galacto-oligosaccharides and inulin with a reasonable expectation for success in providing a prebiotic benefit to the user thereof. The implicit and

understood definition of oligo- (component A) and polysaccharide (component B) is hereby applied.

11. Cavaliere fails to teach a composition wherein two non-digestible soluble carbohydrates are present together wherein one of the carbohydrates is present in an amount of between 60-95% by weight of the sum of the insoluble carbohydrate components.

12. Regardless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Cavaliere with a reasonable expectation for success in arriving at the instantly claimed composition. With respect to the amount of each non-digestible carbohydrate, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Moreover, if one were to combine both of the obvious non-digestible carbohydrates into a prebiotic composition, one would have been motivated to identify an optimum ratio between the two since the amount of the non-digestible carbohydrate is a result-effective variable, i.e. a variable which achieves a recognized result such as enhanced growth of *Bifidobacterium*. Thus, the determination of the optimum or workable ranges of said variable (i.e. improved prebiotic benefit) would be characterized through routine experimentation. See MPEP 2144.05. With respect to the chain length of component A, a galacto-oligosaccharide would readily be envisaged to be a saccharide polymer comprising less than 9 galactose monomers and a fructo-polysaccharide would be envisaged as containing *many* more units than that of an oligosaccharide, let alone 5 saccharide units. One of ordinary skill would have been motivated to adjust the number of saccharide unit for the oligosaccharide so as to provide the greatest nourishing benefit to the end user. If it were found that a oligosaccharide

with between 2 and 6 units was most effective, then this would have been a result of ordinary skill and common sense. Any ordinary person of skill in the art would readily recognize the implicit definitions understood for both oligosaccharides and polysaccharides and apply them accordingly. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/
Examiner, Art Unit 1611
October 25, 2011*

*/Allison M. Ford/
Primary Examiner, Art Unit 1653*